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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,746	12/27/2000	Thomas Specht	SCH 1761	6674

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EXAMINER
SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
1634	

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15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/623,746	Specht
Examiner	**Art Unit**
Jehanne Souaya	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 20, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above, claim(s) *1-22 and 26-37* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *23-25* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group III, SEQ ID NO: 173 in Paper No. 14 is acknowledged. The traversal is on the ground(s) that the examiner has not established an undue searching burden. This is not found persuasive because an undue search burden exists in searching each patentably distinct sequence as well as each sequence in the context of the claimed distinct inventions as set forth in the previous restriction requirement. Therefore, because an undue search burden exists, and because the inventions as well as the sequences are patentably distinct and do not relate to a single general inventive concept for the reasons made of record in the previous office action, the requirement is still deemed proper and is therefore made FINAL.

The following office action on the merits is directed to claims 23-25 and SEQ ID NO 173, claims 1-22 and 26-37, and sequences other than SEQ ID 173 being withdrawn from consideration as drawn to non elected inventions. The claims should be amended accordingly to remove non elected inventions. It is further noted that claims 24 and 25 are dependent on claim 22 instead of claim 23, however, due to the language in the preamble ("polypeptide partial sequences") the examiner included claims 24 and 25 in Group III in the previous restriction requirement because the examiner assumed that such dependency was in error and that the claims were intended to be dependent on claim 23 which states "polypeptide partial sequences" whereas claim 22 is drawn to an antibody and does not recite the preamble "polypeptide partial

sequences". The following rejections are therefore drawn to claims 24 and 25 as being dependent on claim 23. If it is applicant's intent that the claims should be dependent on claim 23, appropriate correction is required. However, if it is applicant's intent that the claims should be dependent on claim 22, the rejection of such claims will be withdrawn as the claims 24 and 25 will be withdrawn from consideration as being directed to non elected subject matter.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (ie: see p. 95). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Appropriate correction is required.

3. The disclosure is objected to because it contains table column headings in a language other than English. See MPEP § 608.01 "Filing of Non-English Language Applications". It is noted that a table is also present that includes the column headings in English. Applicant should delete the table headings in the Non-English Language and include only the English headings. Appropriate correction is required.

Claim Objections

4. Claims 24 and 25 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to

cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is noted that the objection assumes that the dependency of claims 24 and 25 to claim 22 is in error and that the claims are dependent on claim 23. Claims 24 and 25, directed to sequences with 80% or 90% homology according to SEQ ID NO 173 are broader in scope than Claim 23.

Claim Rejections - 35 USC § 112

Enablement

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 23-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide consisting of the sequence of SEQ ID NO 173, does not reasonably provide enablement for partial polypeptide sequences according to SEQ ID NO: 173 or to sequences that have 80% or 90% homology to such. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

It is noted that the following rejection assumes that the dependency of claims 24 and 25 to claim 22 is in error and that the claims are dependent on claim 23.

The claims are broadly drawn to "polypeptide partial sequences according to SEQ ID NO 173" (claim 23) and to polypeptide partial sequences with at least 80% or 90% homology to such. The specification does not define the term "polypeptide partial sequences", therefore, it cannot be determined if the term refers to "open" terminology, that is amino acid sequences on either side of SEQ ID NO 173 (not necessarily including SEQ ID NO 173- due to indefinite term "according to"-see 112/2nd paragraph rejection below), "closed terminology", that is the exact sequence of SEQ ID NO 173, or sequences within SEQ ID NO 173. Consequently, the recitation has been interpreted to encompass all three possibilities. The specification teaches the exact sequence of SEQ ID NO 173, and teaches that the expression of SEQ ID NO 47, which encodes SEQ ID NO 173, is elevated in normal prostatic, hepatic, and ovarian tissue (p 103). The specification teaches that SEQ ID NO 47 is only a partial cDNA sequence, and does not teach the function of SEQ ID NO 173 (see Sequence Listing). Furthermore, the specification does not define the term "homology", therefore it is unclear if the claim refers to sequences that have a certain % identity to partial sequences of SEQ ID NO 173 (that is exact amino acid matches), or to sequences that have a certain % similarity to SEQ ID NO 173 (that is, exact amino acid matches are not required for a certain position, only "similar" amino acids). Consequently, the term has been broadly interpreted to encompass the latter. Thus, claims 24 and 25 broadly encompass mutants, allelic variants, and homologs of SEQ ID NO 173, from any source. The specification, however, has only taught the single sequence of SEQ ID NO 173, and has not taught the activity of SEQ ID NO 173, thus the skilled artisan would not be able to determine which sequences were functional

equivalents or variants of SEQ ID NO: 173, other than by SEQ ID NO. It is known for nucleic acids as well as for protein sequences that a single nucleic acid or amino acid change can abolish the activity of a given protein and that such effects are unpredictable in many, albeit not in all, cases (see Proudfoot et al, Journal of Biological Chemistry, vol. 271, pp 2599-2603, which teaches that extension of recombinant human RANTES by a single residue [Met-RANTES] at the amino terminus was sufficient to produce a potent and selective antagonist - see abstract). Given that the specification does not teach the function of the polypeptide of SEQ ID NO 173 and it's association to prostate cancer such analyses would require trial and error, thus constituting undue experimentation. Furthermore, irrespective of how "% homology" is defined, it is clear that by any definition of "% homology", the many sequences encompassed by applicant's claims, and particularly those having "at least 80% or 90% homology" with sequences larger than SEQ ID NO 173 (which have not been taught) or with fragments of the sequences taught in the specification, would bear little resemblance to the single SEQ ID NO 173 that the specification discloses. Neither the specification nor the claims set forth any particular structural or functional characteristics that a skilled artisan could use to identify polypeptides that constitute the claimed partial polypeptides, other than those described by SEQ ID NO. Furthermore, in teaching a single partial polynucleotide sequence (SEQ ID NO 47) and a single partial protein sequence (SEQ ID NO 173), applicant clearly has not taught the isolation of a representative number of polypeptides that fall within the scope of the large genus encompassed by the instant claims. Thus, while the teachings of the specification and of the prior art would

enable a skilled artisan to make polypeptides consisting of SEQ ID NO: 173, it is unpredictable as to whether a skilled artisan could make and use partial polypeptide sequences having "at least 80% or 90% homology" with SEQ ID NO: 173 or sequences larger than, or fragments thereof. It would require undue experimentation for a skilled artisan to make and use the invention commensurate in scope with the claims.

Written Description

7. Claims 23-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is noted that the following rejection assumes that the dependency of claims 24 and 25 to claim 22 is in error and that the claims are dependent on claim 23.

The claims are broadly drawn to "polypeptide partial sequences according to SEQ ID NO 173" (claim 23) and to polypeptide partial sequences with at least 80% or 90% homology to such. The specification does not define the term "polypeptide partial sequences", therefore, it cannot be determined if the term refers to "open" terminology (note: due to the indefinite term "according to", this does not necessarily include SEQ ID NO 173, see 112/2nd paragraph rejection below), that is amino acid sequences on either side of SEQ ID NO 173, "closed terminology", that is the exact sequence of SEQ ID NO 173, or sequences within SEQ ID NO 173. Consequently, the recitation has been interpreted to encompass all three possibilities. The specification teaches the

exact sequence of SEQ ID NO 173, and teaches that the expression of SEQ ID NO 47, which encodes SEQ ID NO 173, is elevated in normal prostatic, hepatic, and ovarian tissue (p 103). The specification teaches that SEQ ID NO 47 is only a partial cDNA sequence, and does not teach the function of SEQ ID NO 173 (see Sequence Listing). Furthermore, the specification does not define the term "homology", therefore it is unclear if the claim refers to sequences that have a certain % identity to partial sequences of SEQ ID NO 173 (that is exact amino acid matches), or to sequences that have a certain % similarity to SEQ ID NO 173 (that is, exact amino acid matches are not required for a certain position, only "similar" amino acids). Consequently, the term has been broadly interpreted to encompass the latter. Irrespective of how % homology is defined, it is clear that claims 24 and 25 broadly encompass mutants, allelic variants, and homologs of SEQ ID NO 173, from any source. The specification, however, has only taught the single sequence of SEQ ID NO 173, and has not taught the activity of SEQ ID NO 173, thus the skilled artisan would not be able to determine which sequences were functional equivalents or variants of SEQ ID NO: 173, other than by SEQ ID NO. In teaching a single partial polynucleotide sequence (SEQ ID NO 47) and a single partial protein sequence (SEQ ID NO 173), applicant clearly has not taught the isolation of a representative number of sequences larger than SEQ ID NO 173 (encompassed by claim 23) or partial polypeptide mutants, variants, or homologous polypeptide sequences of such, from any source (encompassed by claims 24 and 25), that fall within the scope of the large genus encompassed by the instant claims. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The

specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 173, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The polypeptide itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary

skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Accordingly, the specification does not provide a written description of the invention of claims 23-25.

Indefinite

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 23-25 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23-25 are indefinite in the recitation of "polypeptide partial sequences according to...". The specification does not define the term "polypeptide partial sequences", therefore it cannot be determined if the term refers to "open" terminology, that is SEQ ID NO 173 and amino acid sequences on either side of SEQ ID NO 173, "closed terminology", that is the exact sequence of SEQ ID NO 173, or sequences smaller than SEQ ID NO 173. Furthermore, it cannot be determined from the recitation of "according to" as to whether this terminology refers to only

exact matches to SEQ ID NO 173 or within SEQ ID NO 173 or whether it encompasses undisclosed amino acid sequences that belong to the full length protein of SEQ ID NO 173 (that is, the full length protein that SEQ ID NO 173 is part of). Therefore, the metes and bounds of the claim are unclear.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. It is noted that the following rejections assume that the dependency of claims 24 and 25 to claim 22 is in error and that the claims are dependent on claim 23.

12. Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by accession number S07099 (2/17/1997).

Accession number S07099 teaches fragments of rabbit membrane alanyl aminopeptidase which has greater than 80% identity to SEQ ID NO 173 (alignment provided). Thus the

accession number teaches a partial polypeptide sequence that has at least 80% homology according to SEQ ID NO 173.

13. Claims 23-25 is rejected under 35 U.S.C. 102(b) as being anticipated by Nunez et al. (FEBS Letters, vol. 329, pp 84-88, 1993).

Nunez teaches the partial N terminal sequence (amino acids 1-34) of aminopeptidase N (see p. 86, fig 2). It is noted that SEQ ID NO 173 is a partial polypeptide sequence of human aminopeptidase N (alignment provided for accession number A30325 and SEQ ID NO 173). The examiner has broadly interpreted the term "according to" to include sequences of the full protein sequence that SEQ ID NO 173 is a part of. Therefore, Nunez teaches a partial polypeptide sequence "according to" SEQ ID NO 173 as well as partial polypeptide sequence with at least 80% or 90% identity "according to" SEQ ID NO 173.

14. Claims 23-25 is rejected under 35 U.S.C. 102(b) as being anticipated by Look et al, (J. Clin. Invest. Vol. 83, pp 1299-1307, 1989).

Look et al teach a partial polypeptide sequence (fig. 2, underlined Asn-Ala-Thr, amino acids 818-820 of human aminopeptidase N) that is within SEQ ID NO 173. It is noted that SEQ ID NO 173 is a partial polypeptide sequence of human aminopeptidase N (alignment provided for accession number A30325 and SEQ ID NO 173). As claim 23 does not specify the metes and bounds of the term "partial polypeptide sequence", the term has been broadly interpreted to

encompass sequences within SEQ ID NO 173, which are taught by Look. Such also satisfies the requirement of claims 24 and 25 drawn to partial polypeptide sequence with at least 80% or 90% identity "according to" SEQ ID NO 173.

Conclusion

15. No claims are allowable over the cited prior art.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1634
9/6/2002